

K081584  
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510(k) Summary  
for

JUN 19 2008

**Derma Sciences OTC APIMED, MediHoney Primary and MediHoney  
100% Honey Dressings with Active Manuka Honey**

**1. SPONSOR**

Derma Sciences  
214 Carnegie Center  
Suite 100  
Princeton, NJ 08540

Contact Person: Barry Wolfenson  
Derma Sciences  
214 Carnegie Center, Suite 100  
Princeton, NJ 08540  
Telephone: 609.514.4744 x1103

Date Prepared: June 9, 2008

**2. DEVICE NAME**

Proprietary Name: OTC Derma Sciences APIMED, MediHoney Primary, and MediHoney 100% Honey Dressings with Active Manuka Honey  
Common/Usual Name: Wound Dressing  
Classification Name: Dressing

**3. PREDICATE DEVICES**

- API-MED Active Manuka Honey Wound Dressing that was cleared for marketing in the U.S. (K053095). (now called MediHoney)
- MediHoney Primary Dressings with Active Manuka (*Leptospermum*) Honey in a hydrocolloid sheet (K072956)
- MediHoney Active Manuka (*Leptospermum*) 100% Honey dispensed from a tube 510(k) premarket notification (K080315)
- OTC Dermaphylyx Calcium Alginate Wound Dressings (K991608)
- OTC CuraPharm Phytacare Sodium Alginate Wound Dressing (K053538)
- OTC NOCC Wound Gel Dressing cleared under K080010

- OTC and Rx Aquacel Ag Wound dressing cleared under K013814.

#### 4. DEVICE DESCRIPTION

The Derma Sciences OTC MediHoney Dressings (APIMED, MediHoney Primary and MediHoney 100% Gel) with Active Manuka Honey are designed to provide a moist environment conducive to wound healing and are indicated abrasions, minor burns, minor cuts and minor lacerations.

The Derma Sciences OTC MediHoney Dressings with Active Manuka Honey are sterile, single-use wound care dressings for use in moist wound management. The Derma Sciences OTC MediHoney APIMED Primary Dressings with Active Manuka Honey are offered in several sizes including the following: 2x2, 4x4,  $\frac{3}{4}$  x 12, The OTC MediHoney Primary Dressings with Active Manuka Honey are offered in 1.5" x 2", 2" x 2", 4" x 5", and 2"x3" sizes and are offered both with and without an adhesive backing. The OTC MediHoney 100% Honey Gel Dressings are offered in .5, 1, and 1.5 oz. sizes.

The proposed OTC MediHoney Dressings with Active Manuka Honey are identical in fundamental technology and very similar in indications to the parent API-MED Active Manuka Honey Dressings described in K053095, the MediHoney Primary Dressings with Active Manuka (*Leptospermum*) Honey in a hydrocolloid sheet (K072956) and the MediHoney Active Manuka (*Leptospermum*) 100% Honey dispensed from a tube pending 510(k) premarket notification (K080315). The modifications made to the API-MED, MediHoney Primary and MediHoney 100% Gel Active Manuka Honey Dressings to produce the Derma Sciences OTC MediHoney Dressings with Active Manuka Honey are limited to a slight change in indications and over the counter use. The formulation and function are identical to that described in the original 510(k)'s.

#### 5. INTENDED USE

For over the counter use, MEDIHONEY™ APIMED, PRIMARY and 100% HONEY Dressings with Active Manuka Honey may be used for:

- minor abrasions
- lacerations
- minor cuts
- minor scalds and burns

Under the supervision of a healthcare professional, The Derma Sciences Apimed (MediHoney) Dressings are all indicated for moderate to heavily exuding wounds. The MediHoney Primary Wound Dressings are indicated for lightly to moderately

exuding wounds. The Medihoney 100% Honey Dressings are indicated for non-exuding to moderately exuding wounds. All of the Medihoney Wound Dressings are intended for the management of the following:

- diabetic foot ulcers
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- pressure ulcers / sores (partial and full thickness)
- 1st and 2nd degree partial thickness burns
- donor sites and traumatic and surgical wounds.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of the proposed Derma Sciences OTC Medihoney Dressings with Active Manuka Honey and the parent API-MED, Medihoney Primary and Medihoney 100% Active Manuka Honey Wound Dressings are substantially equivalent in that they are the same dressings with the identical technology and formulation. No changes have been made to the physical device or specifications for the proposed OTC Medihoney Wound Dressings.

The modifications made to the API-MED, Medihoney Primary and Medihoney 100% Active Manuka Honey Dressings to produce the Derma Sciences OTC Medihoney Dressings with Active Manuka Honey are limited to a slight change in indications and over the counter use. The proposed OTC Medihoney Wound Dressings are formulated from the exact same composition as the predicate devices described in the predicate API-MED Active Manuka Honey Wound Dressing, (K053095) (now called Medihoney), the Medihoney Primary Dressings with Active Manuka (*Leptospermum*) Honey in a hydrocolloid sheet (K072956) and the Medihoney Active Manuka (*Leptospermum*) 100% Honey Dressing.

## 7. PERFORMANCE TESTING

Biocompatibility testing performed to support the dressings demonstrates that the Medihoney Primary Dressings with Active Manuka Honey are safe for their intended use. Cytotoxicity, sensitization, irritation and implantation testing was performed successfully using the Derma Sciences Wound Dressings.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 19 2008

Derma Sciences, Inc.  
% Medical Device Consultants, Inc.  
Ms. Mary McNamara-Cullinane  
49 Plain Street  
North Attleboro, Massachusetts 02760

Re: K081584

Trade Name: Derma Sciences OTC MediHoney Dressings with Active Manuka Honey  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: June 5, 2008  
Received: June 6, 2008

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Mary McNamara-Cullinane

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K081584

Device Name: Derma Sciences OTC MediHoney Dressings with Active Manuka Honey

Indications for Use:

For over the counter use, MEDIHONEY™ APIMED, PRIMARY and 100% HONEY Dressings with Active Manuka Honey may be used for:

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- 1st and 2nd degree partial thickness burns
- donor sites and traumatic and surgical wounds.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use X  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John R. Ogle for ODE  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K081584